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Original Article

Validity and reliability of the Health-Related Quality of Life Instrument with 8 Items (HINT-8) in Korean breast cancer patients

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ABSTRACT

Objectives: This study evaluated the validity and reliability of the Health-Related Quality of Life Instrument with 8 Items (HINT-8) in postoperative breast cancer patients in South Korea.
Methods: The study included 300 breast cancer patients visiting a tertiary hospital. We measured health-related quality of life (HRQoL) using the HINT-8, the 5-level EQ-5D version (EQ-5D-5L), and the Functional Assessment of Cancer Therapy-Breast (FACT-B). Discriminatory ability, known-group validity, and convergent validity were assessed. Reliability was evaluated with the Cohen kappa, weighted kappa, and intraclass correlation coefficient (ICC).
Results: The EQ-5D-5L indexes ($p < 0.001$) and EQ visual analogue scale (VAS) scores ($p < 0.001$) were significantly higher in subjects with no problems in each item of the HINT-8 than in those with problems. The FACT-B total scores were also higher in subjects without problems on the HINT-8. Older age, lower education level, and comorbidities were associated with a lower HINT-8 index. The HINT-8 index was correlated with the EQ-5D-5L index and the EQ VAS, with correlation coefficients of 0.671 ($p < 0.001$) and 0.577 ($p < 0.001$), respectively. The correlation coefficients between the HINT-8 and the FACT-B ranged from 0.390 to 0.714. The ICC was 0.690 (95% confidence interval, 0.580–0.780).
Conclusion: The HINT-8 showed appropriate validity for capturing HRQoL in postoperative breast cancer patients.

Keywords: Breast neoplasms; Quality of life; Reproducibility of results

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Introduction

Breast cancer has high incidence and mortality rates, ranking first and fifth in incidence and

mortality in world cancer statistics in 2020 [1]. In Korea, breast cancer was the type of cancer with the highest incidence in women in 2016, followed by thyroid cancer [2]. While the age-standardized incidence rate increased from 24.5 (per 100,000 people) in 1999 to 62.5 in 2016, the 5-year observed survival also showed an increasing tendency between 2012 and 2016 [2,3]. Accordingly, assessing health-related quality of life (HRQoL) is critical for capturing patients' experiences, in addition to traditional epidemiological measures such as mortality and survival rates.

There are 2 types of HRQoL measures: generic and disease-specific. Disease-specific instruments, such as the European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30), focus on issues related to a specific illness, whereas generic instruments assess overall health status in a wide range of populations, including healthy individuals [4]. Generic preference-based measures, such as the EQ-5D or the Short Form 6D, are widely used as a trial end-point and to generate utility estimates for economic evaluations [5,6]. However, the broad application of these generic instruments has been criticized due to cultural differences [7]. In light of this criticism, the Health-Related Quality of Life Instrument with 8 Items (HINT-8) was developed to fit the Korean context [8,9].

The psychometric properties of the HINT-8, a generic preference-based instrument, have been studied in the Korean general population [9]. In addition, its value set (a set of preference weights) was developed for use in the Korean population [10]. The HINT-8 can be used to estimate utility weights using this value set in economic evaluations. The Korea National Health and Nutrition Examination Survey (KNHANES), a national surveillance program assessing participants' health and nutritional status, has adopted the HINT-8 to evaluate quality of life since 2019. However, no study has yet investigated the validity and reliability of the HINT-8 in disease-specific populations, such as individuals with cancer. The psychometric properties of the HINT-8 in disease-specific populations should be studied to expand its use for decision-making in the healthcare sector. Therefore, we evaluated the validity and reliability of the HINT-8 in postoperative breast cancer patients in Korea.

Materials and Methods

Subjects and Study Setting

We recruited a consecutive series of 300 breast cancer patients in the ambulatory or inpatient care setting of a tertiary hospital in Seoul, South Korea between April and June in 2018. The target population was women (aged ≥ 30 y) who underwent surgery as a primary treatment for breast cancer. We only included female patients due to the substantial differences between male and female breast cancer, including the rare incidence of this condition in men [3]. Considering differences in patients' characteristics according to the postoperative duration, we categorized the population into 3 groups: group 1 (2–4 days after surgery, n = 50), group 2 (within 5 years after surgery, n = 150), and group 3 (more than 5 years after surgery, n = 100). After obtaining written informed consent from each patient, a paper-based survey was conducted by a trained interviewer in the survey. After 1 to 4 weeks, 100 consecutive participants from the first survey were followed up through a telephone-based survey administered by the same interviewer. Considering fluctuations in HRQoL status during the immediate perioperative period [11], subjects in group 1 (2–4 days after surgery) were excluded from the retest for reliability assessment. The institutional review board of Asan Medical Center approved the study (No. 2018-0026).

Data Collection and HRQoL Assessment

Primary background information about demographics (age, education level, marital status, monthly household income, outpatient visit, hospitalization, and self-rated health) and clinical characteristics (duration of disease, surgery type, current treatment, and comorbidities) was collected from all participating subjects. The HINT-8, as the generic HRQoL instrument of interest, and other widely used instruments including the 5-level EQ-5D version (EQ-5D-5L) and the Functional Assessment of Cancer Therapy-Breast (FACT-B) were used in the initial and follow-up surveys [12,13].

The HINT-8 consists of 8 items (climbing stairs, pain, vitality, working, depression, memory, sleep, and happiness) and 4 levels (no problems, mild, moderate, and severe problems) representing 65,536 health states [8,9], which is a far higher number of states than the 3,125 states gathered by the EQ-5D-5L [14]. The HINT-8 scores range from 0.132 (worst possible health state, 44444444) to 1.000 (best possible health state, 11111111), and the index can be derived from the previously developed value set [10]. The EQ-5D-5L comprises 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and 5 levels (no problems, slight problems, moderate problems, severe problems, and extreme problems) [14]. To derive a utility index from the descriptive system of the EQ-5D-5L, we used the tariff developed in Korea [15,16]. The EQ-5D-5L utility scores using the Korean tariff range from −0.066

(worst possible health state, 55555) to 1 (best possible health state, 11111), with a higher score indicating better health status. In addition to the EQ-5D-5L descriptive system, participants' overall current health status was assessed with the EQ visual analogue scale (EQ VAS) [14]. The EQ VAS ranges from 0 (worst imaginable health state) to 100 (best imaginable health state). The Korean version 4 of FACT-B, a disease-specific instrument, was also used to confirm the validity of the HINT-8 in the population of Korean breast cancer patients [13,17]. The FACT-B consists of 5 subscales: physical well-being (PWB; score range, 0–28), social/family well-being (SWB; score range, 0–28), emotional well-being (EWB; score range, 0–24), functional well-being (FWB; score range, 0–28), and the breast cancer subscale (BCS; score range, 0–40). The FACT-B trial outcome index (TOI; score range, 0–96), FACT-General (FACT-G) total score (score range, 0–108), and FACT-B total score (score range, 0–148) are derived as follows: (1) FACT-B TOI = PWB score+FWB score+BCS score; (2) FACT-G total score = PWB score+SWB score+EWB score+FWB score; and (3) FACT-B total score = PWB score+SWB score+EWB score+FWB score+BCS score. In the FACT-B, a higher score represents better quality of life.

Statistical Analyses

The distribution of responses in each level of the different instruments was calculated, and the ceiling effect of the HINT-8 was examined in comparison with the EQ-5D-5L. To determine the discriminatory ability of the HINT-8, the mean scores of the different measures (EQ-5D-5L index, EQ VAS, and FACT-B total) were compared according to the presence of problems (without problems vs. with problems). The group with problems included participants with mild, moderate, or severe problems, whereas those who reported no problems were included in the group without problems. Regarding discriminative validity, it was assumed that the group reporting problems in the HINT-8 had a poor health state in other HRQoL instruments. To demonstrate the known-group validity of the HINT-8, the HINT-8 index score was evaluated according to sociodemographic and clinical features. We hypothesized that the HINT-8 index would be lower in older and less educated groups [18]. We also evaluated the EQ-5D-5L index scores between relevant groups, and then calculated the relative efficiency (RE) to compare the efficiency of 2 generic instruments to capture relevant differences in breast cancer patients [19]. The RE was defined as the ratio of the squared *t* statistics ($t^2_{HINT\text{-}8}/t^2_{EQ\text{-}5D\text{-}5L}$) or the ratio of ANOVA F statistics ($F_{HINT\text{-}8}/F_{EQ\text{-}5D\text{-}5L}$).

To evaluate convergent validity, the associations of the HINT-8 with the EQ-5D-5L and FACT-B were examined. It was assumed that a specific item of the HINT-8 would correlate more strongly with conceptually relevant categories of the other instruments (i.e., EQ-5D-5L dimensions and FACT-B subscales) than with unrelated ones. The Cohen kappa, weighted kappa coefficient, and intraclass correlation coefficient (ICC) were calculated to identify the reliability of the HINT-8, including individual items and the utility index [20]. A p-value less than 0.05 was considered to indicate statistical significance. Statistical analyses were performed using SAS ver. 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Subject Characteristics

The ages of subjects in the baseline and follow-up tests were 54.4 ± 9.1 and 54.4 ± 8.6 years, respectively (Table 1). Regarding the education level, the largest proportion (46.0%) of participants in the first survey had a university degree or higher, whereas the largest group in the follow-up survey (45.0%) had a secondary education level. The proportion of married participants was 79.7% and 79.0%, respectively. The average monthly household income (Korean won, KRW) was slightly higher in the baseline population than in the retest population (5,080,000 ± 5,160,000 vs. 4,920,000 ± 5,570,000 KRW). The duration of disease after diagnosis was 4.2 ± 4.0 years in the first paper-based survey and 4.8 ± 3.7 years in the second telephone-based survey. Patients who underwent partial mastectomy accounted for the largest proportion of participants in the baseline and follow-up groups (69.7% and 72.0%, respectively). In both rounds of tests, the proportion of patients undergoing current treatment was similar (46.3% vs. 49.0%). The proportions of participants with any comorbidities were 36.7% and 41.0% in the baseline and follow-up tests, respectively.

Distribution of Responses to HRQoL Instruments

The response distribution of individual HINT-8 items is shown in Figure 1A. In the HINT-8, more than 90% of the responses to the items of climbing stairs, pain, working, depression, and memory corresponded to levels 1 and 2 in the first survey, whereas the proportion of responses of levels 1 to 3 was over 90% for the vitality, sleep, and happiness items. The HINT-8 indexes were similar in the first and second surveys (0.801 ± 0.095 vs. 0.813 ± 0.091). The average EQ-5D-5L index was slightly higher than the HINT-8 indexes in both the test and retest results (0.850 ± 0.117 vs. 0.881 ± 0.115). In terms of descriptive responses to the EQ-5D-5L, 89.2% to 94.4% of participants responded with levels

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Table 1. General and clinical characteristics

Characteristic	Baseline (*n* = 300)	Follow-up (*n* = 100)
Age (y)	54.4 ± 9.1	54.4 ± 8.6
30–49	93 (31.0)	28 (28.0)
50–59	119 (39.7)	42 (42.0)
≥ 60	88 (29.3)	30 (30.0)
Level of education		
Less than intermediate school	46 (15.3)	19 (19.0)
Secondary school	116 (38.7)	45 (45.0)
University degree or higher	138 (46.0)	36 (36.0)
Marital status		
Married	239 (79.7)	79 (79.0)
Others	61 (20.3)	21 (21.0)
Monthly household income (₩10,000)	508 ± 516	492 ± 557
Q1 (*n* = 85)	124 ± 64	115 ± 66
Q2 (*n* = 75)	327 ± 65	312 ± 56
Q3 (*n* = 72)	555 ± 60	519 ± 65
Q4 (*n* = 68)	1,136 ± 740	1,091 ± 891
Outpatient visit in the past 2 weeks		
Yes	92 (30.7)	35 (35.0)
No	208 (69.3)	65 (65.0)
Hospitalization in the past 1 year		
Yes	71 (23.7)	22 (22.0)
No	229 (76.3)	78 (78.0)
Self-rated health		
Very good/good	100 (33.3)	33 (33.0)
Moderate/poor/very poor	200 (66.7)	67 (67.0)
Postoperative duration	4.2 ± 4.0	4.8 ± 3.7
2–5 day (*n* = 50)	50 (16.7)	0
< 5 y (*n* = 150)	150 (50.0)	60 (60.0)
≥ 5 y (*n* = 100)	100 (33.3)	40 (40.0)
Surgery		
Total mastectomy	60 (20.0)	17 (17.0)
Partial mastectomy	209 (69.7)	72 (72.0)
Reconstruction	31 (10.3)	11 (11.0)
Current treatment		
Yes	139 (46.3)	49 (49.0)
No	161 (53.7)	51 (51.0)
Comorbidity		
Yes	110 (36.7)	41 (41.0)
No	190 (63.3)	59 (59.0)

Data are presented as mean ± standard deviation or *n* (%).
₩, Korean won.

1 and 2, except in the domain of self-care in the first round, and 88.0% to 95.0% in the second round of tests (Figure 1B); 92.0% and 91.0% of respondents reported no problems (level = 1) for the item of self-care. The mean ± standard deviation (SD) of the total score of the FACT-B was 104.76 ± 20.73 and the TOI was 68.16 ± 13.66 in the baseline test (Figure 1C).

In the EQ-5D-5L, 21.0% of respondents reported the best possible health state (11111), whereas only 2.3% reported the best health state (11111111) in the HINT-8 (Table S1). The EQ VAS score of subjects who reported the best possible health state in the HINT-8 was 4.63 points higher than that of subjects with the corresponding state in the EQ-5D-5L. The respondents reporting the best possible health state in the HINT-8 showed higher FACT-B scores than those with a perfect health state in the EQ-5D-5L. The FACT-B total scores differed by 6.03 between subjects who reported a perfect health status in the 2 HRQoL instruments (i.e., HINT-8 and EQ-5D-5L).

Validity and Reliability

The results of discriminatory ability testing showed that subjects who reported no problems on the HINT-8 had higher scores in the EQ-5D-5L and EQ VAS than those with problems, and the differences were significant ($p < 0.001$) (Table 2). The discriminatory ability of the HINT-8 was also demonstrated in the FACT-B measures, and the differences were mostly significant, except in the memory and sleep items of the HINT-8 (Figure S1). The results of the test for determining the differences between groups to evaluate known-group validity are presented in Figure 2 (HINT-8) and Figure S2 (EQ-5D-5L). The results were consistent with the hypotheses for the HINT-8: older patients and less educated patients had significantly lower HINT-8 indexes than those in other groups. The current treatment group had a slightly lower HINT-8 index than the others (0.794 vs. 0.804), although the difference was not statistically significant ($p = 0.755$). There was a trend toward lower HINT-8 index scores in subjects with comorbidities than in subjects without any comorbidity, but this trend did not reach statistical significance (0.779 vs. 0.811, $p = 0.059$). In terms of EQ-5D-5L, while the results were consistent with our hypotheses for age groups (age 30–49 y, 0.848; age 50–59 y, 0.842; age ≥ 60 y, 0.827; $p = 0.493$) and comorbidities (yes, 0.813; no, 0.855; $p < 0.001$), there were no significant differences according to education level and marital status, income, and current treatment. The HINT-8 showed better known-group validity than the EQ-5D-5L. The RE statistic was more than 1, denoting better efficiency, for the following characteristics: age groups (RE = 4.63), level of education (RE = 7.20), monthly household income (RE = 2.47), self-rated health (RE = 1.59), and current treatment (RE = 8.09). However, the RE values were lower for marital status (RE = 0.69), hospitalization (RE = 0.94), duration of disease (RE = 0.11), and comorbidities (RE = 0.96), implying poor efficiency of the HINT-8 compared to the EQ-5D-5L. The RE measures of several characteristics indicated

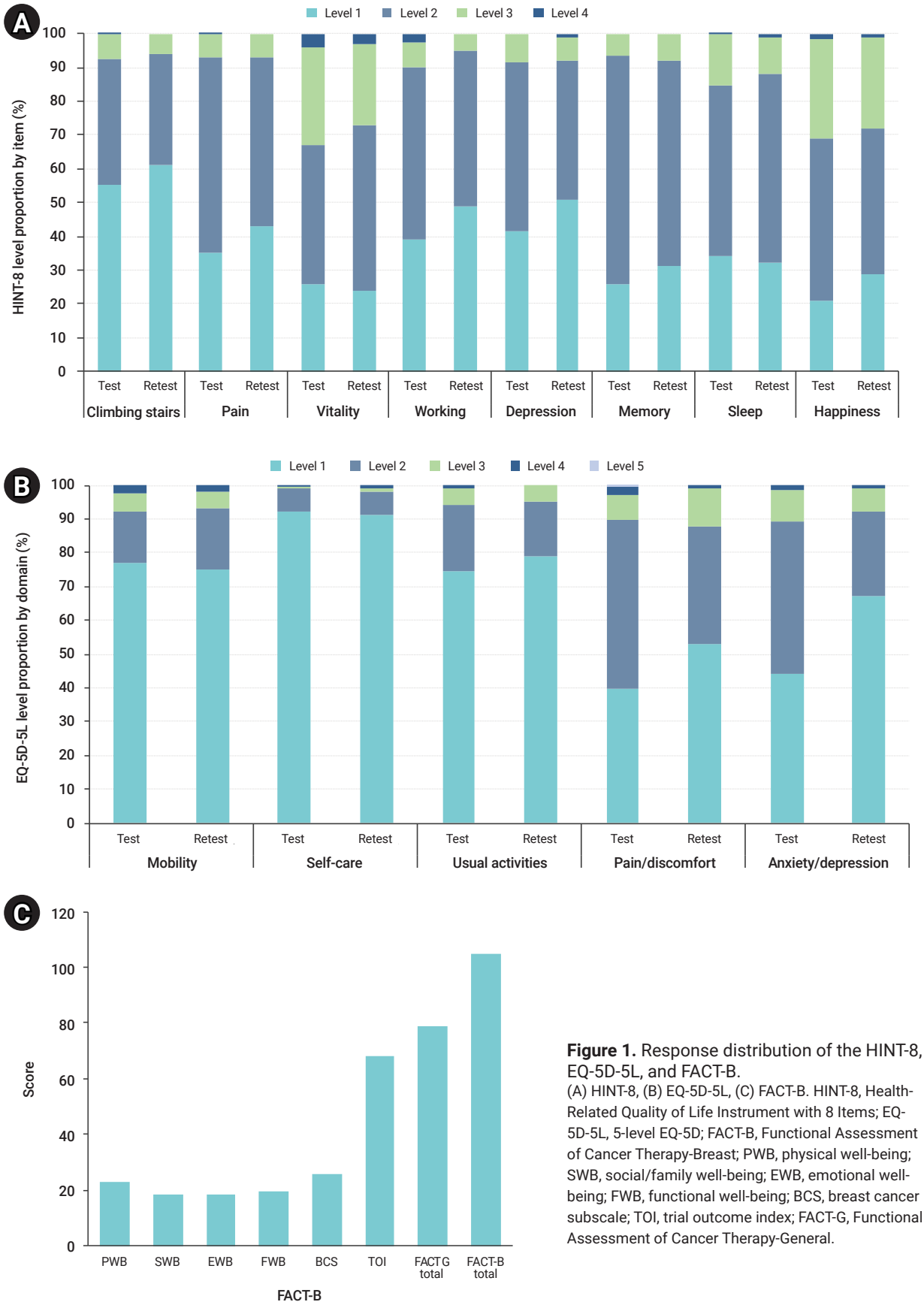

Figure 1. Response distribution of the HINT-8, EQ-5D-5L, and FACT-B.
(A) HINT-8, (B) EQ-5D-5L, (C) FACT-B. HINT-8, Health-Related Quality of Life Instrument with 8 Items; EQ-5D-5L, 5-level EQ-5D; FACT-B, Functional Assessment of Cancer Therapy-Breast; PWB, physical well-being; SWB, social/family well-being; EWB, emotional well-being; FWB, functional well-being; BCS, breast cancer subscale; TOI, trial outcome index; FACT-G, Functional Assessment of Cancer Therapy-General.

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Table 2. Comparison of the EQ-5D-5L index, the EQ VAS, and the FACT-B total score according to the presence of problems in the HINT-8

HINT-8 item	Level[a)]	*n*	EQ-5D-5L index	EQ VAS	FACT-B total
Climbing stairs	1	162	0.878 ± 0.094**	82.29 ± 12.74**	27.71 ± 5.00**
	2 or 3 or 4	138	0.794 ± 0.130	74.86 ± 17.49	23.30 ± 6.29
Pain	1	104	0.901 ± 0.098**	84.01 ± 11.04**	28.14 ± 4.86**
	2 or 3 or 4	196	0.807 ± 0.117	76.14 ± 16.86	24.38 ± 6.20
Vitality	1	78	0.891 ± 0.114**	84.68 ± 13.05**	27.36 ± 5.54*
	2 or 3 or 4	222	0.821 ± 0.116	76.83 ± 15.85	25.09 ± 6.10
Working	1	121	0.891 ± 0.088**	83.84 ± 11.59**	27.97 ± 4.87**
	2 or 3 or 4	179	0.805 ± 0.125	75.51 ± 16.93	24.14 ± 6.26
Depression	1	117	0.899 ± 0.094**	85.12 ± 11.08**	28.02 ± 4.90**
	2 or 3 or 4	183	0.802 ± 0.119	74.87 ± 16.65	24.19 ± 6.23
Memory	1	81	0.887 ± 0.097**	83.28 ± 12.60**	27.70 ± 4.74**
	2 or 3 or 4	219	0.822 ± 0.122	77.24 ± 16.21	24.94 ± 6.30
Sleep	1	101	0.877 ± 0.098**	83.55 ± 10.95**	26.94 ± 5.36*
	2 or 3 or 4	199	0.821 ± 0.125	76.49 ± 16.94	25.05 ± 6.27
Happiness	1	60	0.899 ± 0.105**	88.18 ± 9.10**	27.83 ± 5.26*
	2 or 3 or 4	240	0.825 ± 0.118	76.54 ± 15.95	25.15 ± 6.11

Data are presented as mean ± standard deviation.
EQ-5D-5L, 5-level EQ-5D; EQ VAS, EQ visual analogue scale; FACT-B, Functional Assessment of Cancer Therapy-Breast; HINT-8, Health-Related Quality of Life Instrument with 8 Items.
[a)]Without problems: level 1, no problems; with problems: level 2, mild; level 3, moderate; level 4, severe problems.
*$p < 0.05$, **$p < 0.001$.

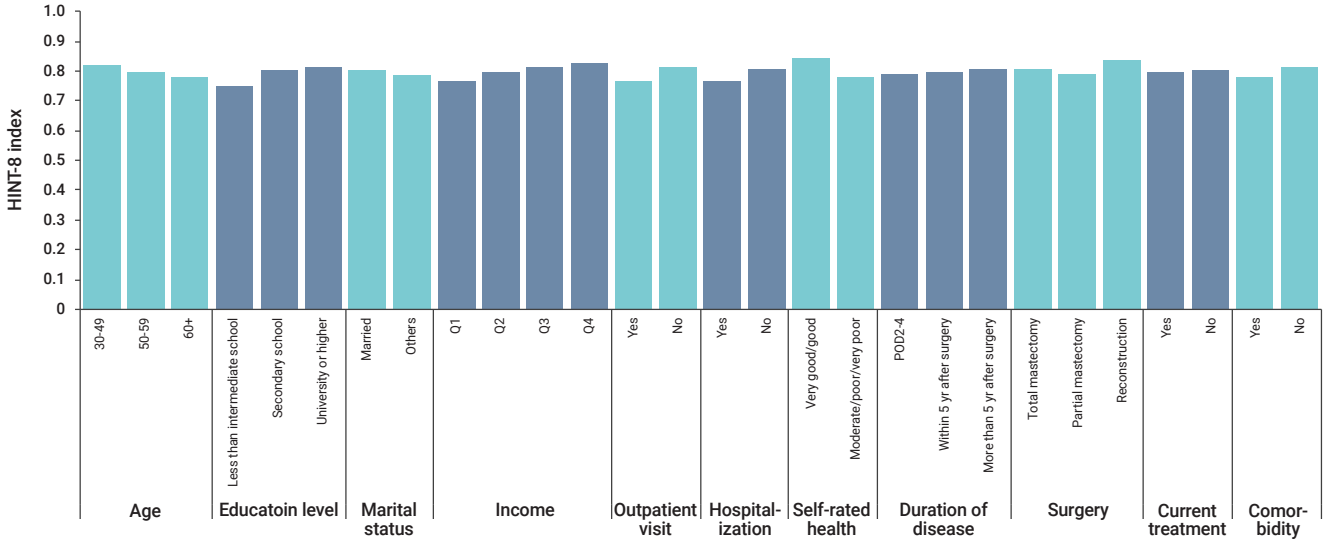

Figure 2. Mean scores of HINT-8 indexes according to general and clinical characteristics.
All *p*-values less than 0.05 except marital status (p=0.760), duration of disease (p=0.471), current treatment (p=0.755), and comorbidities (p=0.059). HINT-8, Health-Related Quality of Life Instrument with 8 Items; Q, quartile; POD, postoperative day.

similar efficiency (outpatient visit, RE = 1.21; surgery, RE = 1.05). The results of the correlation analysis between the HINT-8 and the other instruments are presented in Tables 3 and 4. The climbing stairs item showed an almost strong correlation with the mobility domain of the EQ-5D-5L ($r = 0.493$, $p < 0.001$). The working item of the HINT-8 showed moderate to strong correlations with the dimensions of mobility, usual activities, and pain/discomfort. There was a strong correlation between the depression item of the HINT-8 and the anxiety/depression domain of the EQ-5D-

Table 3. Correlation coefficients between the HINT-8 and the EQ-5D-5L

HINT-8	Mobility	Self-care	Usual activities	Pain/ discomfort	Anxiety/ depression	EQ-5D-5L index	EQ VAS
Climbing stairs	0.493**	0.165*	0.321**	0.365**	0.241**	−0.440**	−0.227**
Pain	0.407**	0.135*	0.373**	0.600**	0.290**	−0.553**	−0.310**
Vitality	0.311**	0.104	0.249**	0.290**	0.331**	−0.377**	−0.373**
Working	0.454**	0.108	0.419**	0.429**	0.338**	−0.505**	−0.338**
Depression	0.264**	0.162*	0.255**	0.224**	0.727**	−0.453**	−0.378**
Memory	0.206**	0.035	0.166*	0.318**	0.198**	−0.303**	−0.191**
Sleep	0.182*	0.175*	0.257**	0.263**	0.301**	−0.307**	−0.283**
Happiness	0.246**	0.071	0.229**	0.243**	0.511**	−0.376**	−0.461**
HINT-8 index	−0.473**	−0.158**	−0.435**	−0.581**	−0.561**	*0.671***	*0.577***

All coefficients were derived by Spearman correlation analysis except for those of the HINT-8 index with the EQ-5D-5L index and the EQ VAS (Pearson correlation). Pearson correlation coefficients are in italics.
HINT-8, Health-Related Quality of Life Instrument with 8 Items; EQ-5D-5L, 5-level EQ-5D; EQ VAS, EQ visual analogue scale.
*$p < 0.05$, **$p < 0.001$.

Table 4. Correlation coefficients between the HINT-8 and the FACT-B

HINT-8	PWB	SWB	EWB	FWB	BCS	TOI	FACT-G total	FACT-B total
Climbing stairs	−0.367**	−0.148*	−0.207**	−0.287**	−0.374**	−0.402**	−0.303**	−0.347**
Pain	−0.582**	−0.202**	−0.253**	−0.375**	−0.368**	−0.501**	−0.413**	−0.439**
Vitality	−0.469**	−0.211**	−0.330**	−0.358**	−0.230**	−0.407**	−0.406**	−0.397**
Working	−0.566**	−0.219**	−0.272**	−0.414**	−0.357**	−0.519**	−0.431**	−0.456**
Depression	−0.387**	−0.300**	−0.589**	−0.477**	−0.379**	−0.506**	−0.524**	−0.532**
Memory	−0.301**	−0.213**	−0.143*	−0.240**	−0.237**	−0.295**	−0.271**	−0.290**
Sleep	−0.351**	−0.114*	−0.211**	−0.439**	−0.244**	−0.424**	−0.322**	−0.336**
Happiness	−0.357**	−0.445**	−0.474**	−0.545**	−0.350**	−0.512**	−0.570**	−0.566**
HINT-8 index	*0.714***	*0.390***	*0.535***	*0.621***	*0.568***	*0.767***	*0.698***	*0.731***

All coefficients were derived by Spearman correlation analysis except for those of the HINT-8 index with all FACT-B subscale and summary scores (Pearson correlation). Pearson correlation coefficients are in italics.
HINT-8, Health-Related Quality of Life Instrument with 8 Items; FACT-B, Functional Assessment of Cancer Therapy-Breast; PWB, physical well-being; SWB, social/family well-being; EWB, emotional well-being; FWB, functional well-being; BCS, breast cancer subscale; TOI, trial outcome index; FACT-G, Functional Assessment of Cancer Therapy-General.
*$p < 0.05$, **$p < 0.001$.

5L indexes (r = 0.727, $p < 0.001$). The happiness item in the HINT-8 was strongly correlated with the anxiety/depression domain of the EQ-5D-5L (r = 0.511, $p < 0.001$). The HINT-8 index was moderately correlated with individual domains of the EQ-5D-5L (from −0.581 to −0.435) except the self-care domain (r = −0.158). The correlation coefficients of the HINT-8 index with EQ-5D-5L and EQ VAS were 0.671 and 0.577, respectively. The pain and working items in the HINT-8 had a strong relationship with the PWB subscale of the FACT-B (−0.582 and −0.566, respectively). The depression item of the HINT-8 had a strong correlation with the EWB subscale, as well as the FACT-G, FACT-B total score, and TOI. The happiness item of the HINT-8 was strongly correlated with the FWB subscale, in addition to the FACT-G, FACT-B total score, and TOI. In general, there were strong correlations between the HINT-8 indexes and FACT-B subscales and other aggregated scores (i.e., TOI, FACT-G total, and FACT-B total), whereas there was a relatively moderate correlation (r = 0.390) between the HINT-8 index and SWB.

Agreement between surveys ranged from 43.0% to 70.0% (Table 5). The Cohen kappa coefficients of individual items in the HINT-8 ranged from 0.134 to 0.436 and the weighted kappa ranged from 0.249 to 0.513, indicating fair agreement except for the vitality item. The ICC of the HINT-8 index was 0.690 (95% confidence interval [CI], 0.580–0.780).

Discussion

This study compared the psychometric properties of the HINT-8, a newly developed general HRQoL instrument targeting the Korean population, with widely used generic and disease-specific HRQoL instruments. The comparative analysis between subjects with no problems and those with problems on the HINT-8 showed significant differences in

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Table 5. Test-retest reliability of the HINT-8

HINT-8	Kappa (95% CI)	Weighted kappa (95% CI)	Agreement rate (%)
Climbing stairs	0.396 (0.235–0.557)	0.469 (0.316–0.622)	66
Pain	0.428 (0.273–0.584)	0.467 (0.320–0.615)	68
Vitality	0.134 (–0.010–0.277)	0.249 (0.112–0.386)	43
Working	0.428 (0.280–0.577)	0.440 (0.304–0.575)	67
Depression	0.436 (0.281–0.591)	0.513 (0.374–0.652)	68
Memory	0.416 (0.238–0.593)	0.464 (0.293–0.635)	70
Sleep	0.418 (0.257–0.579)	0.499 (0.355–0.644)	66
Happiness	0.390 (0.241–0.539)	0.444 (0.294–0.593)	60
HINT-8 index	0.690 (0.580–0.780)[a]	-	-

HINT-8, Health-Related Quality of Life Instrument with 8 Items; CI, confidence interval.
[a]Intraclass correlation coefficient (95% CI).

the EQ-5D-5L index, EQ VAS, and FACT-B total score; groups reporting no problems had higher scores than the others. The results are interpreted as showing that the response levels of the HINT-8 meaningfully distinguish between the levels of specific health states. The results of known-group validity were consistent with those of a previous validity study of the EQ-5D-3L with respect to age and education level [5,21]. The hypotheses related to the known-group validity of the HINT-8 were mostly verified; younger, more highly educated subjects and patients with a longer disease duration showed a better HRQoL status. However, the differences between patients according to the duration of disease were not significant ($p = 0.471$). This non-significant difference was also observed in clinical features such as current treatment and comorbidities. The lack of statistical significance may be related to the small sample sizes of individual subgroups, which occurred because of resource restrictions and efforts to recruit a wide spectrum of patients with different HRQoL statuses based on previous studies [22–26]. Considering the RE statistics between the HINT-8 and the EQ-5D-5L, the HINT-8 showed better or similar known-group validity for most characteristics (RE statistics, range: 0.69–8.09), with the only exception being the duration of disease (RE = 0.11).

The comparison between the HINT-8 and the EQ-5D-5L showed strong correlations between the 2 relevant areas such as pain and depression (r = 0.600 and r = 0.727, respectively). Moreover, the correlation between the utility indexes of the 2 generic instruments (i.e., HINT-8 and EQ-5D-5L) was also strong (r = 0.671). The correlation coefficients between the HINT-8 index and the FACT-B (FACT-B subscales and total score) were 0.390–0.731 in current study. In previous studies, the correlations between the EQ-5D-3L index and FACT-B were strongest in SWB and weakest in FACT-B total scores, with ranges of 0.11–0.56 reported by Lee et al. [27] and 0.199–0.557 by Kim et al. [5], respectively. The HINT-8 showed a good correlation with the EQ-5D-5L in general. In addition, correlations of the HINT-8 with the FACT-B were better than the EQ-5D-3L. The results support the feasibility of using the HINT-8 instead of the EQ-5D-5L, a currently widely used tool in decision-making such as economic evaluations in patients with breast cancer.

The reliability of the categorical variables of the HINT-8 was acceptable, with weighted kappa coefficients of 0.249–0.513; using the cutoff points proposed by Landis and Koch [28], these values are interpreted as indicating fair or moderate agreement [29,30]. The overall Cohen kappa values derived from this study were lower than those of a previous study in the general population (0.565–0.799) [10]. The ICC of the HINT-8 index between the test and the retest (0.690; 95% CI, 0.580–0.780) was also to some extent lower than the outcomes derived from the HINT-20 and the HINT-8 (0.813 and 0.853, respectively) [10,20]. These inconclusive results regarding reliability may be attributed to differences in the survey administration methods between the baseline and the follow-up survey. A similar pattern was reported in the prior study of the EQ-5D-5L that used different survey administration methods; the kappa values of individual domains of the EQ-5D-5L ranged from 0.206 to 0.446 and the ICC was 0.626 [30]. Although the telephone interview method has been reported as equivalent to patient-completed surveys, variations in the agreement between individual domain scores were reported by Chatterji et al. [31].

A strength of the HINT-8 is the inclusion of a greater number of health states (65,536 health states) than those included in commonly used generic tools such as EQ-5D-3L and EQ-5D-5L [9,10]. Compared with the EQ-5D-5L, the HINT-8 showed good properties related to the ceiling effect.

Only 2.3% of participants reported a perfect health state in the HINT-8, whereas the corresponding proportion was 21.0% in the EQ-5D-5L. In addition, the EQ VAS score of the group with the full health state measured by the HINT-8 was higher than in the EQ-5D-5L (EQ VAS 93.00 vs. 88.37, respectively). These results indicate that the HINT-8 may be a more elaborate tool representing diverse health states that is superior for capturing changes in HRQoL among relatively healthy individuals. Considering the proper level of validity and better results in certain aspects including more informative health states, the HINT-8 is a usable tool to evaluate HRQoL in patients with breast cancer.

Despite the overall good psychometric properties of the HINT-8, this study has several limitations. First, the results should be generalized with caution because all subjects were recruited consecutively in either the ambulatory or inpatient units of a single tertiary hospital. Second, patients were enrolled into 3 subgroups according to the duration of disease (group 1, 2–4 days after surgery; group 2, within 5 years after surgery; group 3, more than 5 years after surgery) with predesignated numbers of samples in each subgroup. Resource restrictions and the variety of patients with clinical conditions affecting HRQoL resulted in small sizes in the different groups. Lastly, the use of different survey methods in the baseline and the follow-up tests may have affected the reliability of the results. The first test consisted of a paper-based survey administered in the hospital setting, including outpatient clinics and inpatient wards, whereas the follow-up survey was conducted through personal mobile devices. The use of mobile devices implies that participants were in a variety of locations at the time of the second survey, which might have affected the reliability of the test. The use of the same survey mode may improve the reliability of the instruments in future studies. Furthermore, future studies are needed both to assess the impact of different survey methods and to investigate tactics for minimizing the effects resulting from the use of different survey methods.

In conclusion, our study showed the HINT-8 is applicable to Korean women recovering from breast cancer surgery as a measurement of HRQoL. In particular, the HINT-8 showed better properties than the EQ-5D-5L in certain aspects such as known-group validity. Considering the inconclusive findings regarding reliability, its reliability should be more investigated in further research.

Supplementary Material

Table S1: Analysis of ceiling effects; Figure S1: Difference of FACT-B score between groups reporting with problems and without problems for each HINT-8 item; Figure S2: Mean scores of EQ-5D indexes according to general and clinical characteristics. Supplementary data are available at https://doi.org/10.24171/j.phrp.2021.0005.

Notes

Ethics Approval

The institutional review board of Asan Medical Center approved the study (No. 2018-0026). The written informed consent was obtained from all subjects prior to participating in the study.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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Availability of Data

All data generated or analyzed during this study are included in this published article and its supplementary information files. For other data, these may be requested through the corresponding author.

Authors' Contributions

Conceptualization: MWJ, HJL, JWL; Data curation: JK, SHA, BHS, JWL, SBL; Formal Analysis: JK; Funding acquisition: MWJ; Investigation: all authors; Methodology: MWJ, HJL, JWL; Project administration: JK, HJL; Supervision: MWJ; Writing–original draft: JK; Writing–review & editing: all authors.

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